NORFLEX - orphenadrine citrate tablet, extended release
NORFLEX - orphenadrine citrate injection
3M Pharmaceuticals

DESCRIPTION

Orphenadrine citrate is the citrate salt of orphenadrine (2-dimethylaminoethyl 2- methylbenzhydryl ether citrate). It occurs as a white, crystalline powder having a bitter taste. It is practically odorless; sparingly soluble in water, slightly soluble in alcohol.
Each Norflex Extended-release Tablet contains 100 mg orphenadrine citrate. Norflex Extended-release Tablets also contain: calcium stearate, ethylcellulose, and lactose. Norflex Injection contains 60 mg of orphenadrine citrate in aqueous solution in each ampul. Norflex Injection also contains: sodium bisulfite NF, 2.0 mg; sodium chloride USP, 5.8 mg; sodium hydroxide, to adjust pH; and water for injection USP, q.s. to 2 mL.

CLINICAL PHARMACOLOGY

The mode of therapeutic action has not been clearly identified, but may be related to its analgesic properties. Orphenadrine citrate does not directly relax tense skeletal muscles in man. Orphenadrine citrate also possesses anti-cholinergic actions.

INDICATIONS AND USAGE

Orphenadrine citrate is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute painful musculo skeletal conditions.

CONTRAINDICATIONS

Contraindicated in patients with glaucoma, pyloric or duodenal obstruction, stenosing peptic ulcers, prostatic hypertrophy or obstruction of the bladder neck, cardio-spasm (megaesophagus) and myasthenia gravis.
Contraindicated in patients who have demonstrated a previous hypersensitivity to the drug.

WARNINGS

Some patients may experience transient episodes of light-headedness, dizziness or syncope. Norflex may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; ambulatory patients should therefore be cautioned accordingly.
Norflex Injection contains sodium bisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than nonasthmatic people.

PRECAUTIONS

Confusion, anxiety and tremors have been reported in few patients receiving propoxyphene and orphenadrine concomitantly. As these symptoms may be simply due to an additive effect, reduction of dosage and/or discontinuation of one or both agents is recommended in such cases.
Orphenadrine citrate should be used with caution in patients with tachycardia, cardiac decompensation, coronary insufficiency, cardiac arrhythmias.
Safety of continuous long-term therapy with orphenadrine has not been established. Therefore, if orphenadrine is prescribed for prolonged use, periodic monitoring of blood, urine and liver function values is recommended.

PREGNANCY

Pregnancy Category C. Animal reproduction studies have not been conducted with Norflex. It is also not know whether Norflex can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Norflex should be given to a pregnant woman only if clearly needed.

PEDIATRIC USE

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse reactions of orphenadrine are mainly due to the mild anti-cholinergic action of orphenadrine, and are usually associated with higher dosage. Dryness of the mouth is usually the first adverse effect to appear. When the daily dose is increased, possible adverse effects include: tachycardia, palpitation, urinary hesitancy or retention, blurred vision, dilatation of pupils, increased ocular tension, weakness, nausea, vomiting, headache, dizziness, constipation, drowsiness, hypersensitivity reactions, pruritus, hallucinations, agitation, tremor, gastric irritation, and rarely urticaria and other dermatoses. Infrequently, an elderly patient may experience some degree of mental confusion. These adverse reactions can usually be eliminated by reduction in dosage. Very rare cases of aplastic anemia associated with the use of orphenadrine tablets have been reported. No causal relationship has been established.
Rare instances of anaphylactic reaction have been reported associated with the intramuscular injection of Norflex Injection.

DRUG ABUSE AND DEPENDENCE
Orphenadrine has been chronically abused for its euphoric effects. The mood elevating effects may occur at therapeutic doses of orphenadrine.

OVERDOSAGE
Orphenadrine is toxic when overdosed and typically induces anticholinergic effects. In a review of orphenadrine toxicity, the minimum lethal dose was found to be 2-3 grams for adults; however, the range of toxicity is variable and unpredictable. Treatment for orphenadrine overdose is evacuation of stomach contents (when necessary), charcoal at repeated doses, intensive monitoring, and appropriate supportive treatment of any emergent anticholinergic effects.

DOSAGE AND ADMINISTRATION
TABLETS: Adults – Two tablets per day; one in the morning and one in the evening.
INJECTION: Adults – One 2 mL ampul (60 mg) intravenously or intramuscularly; may be repeated every 12 hours. Relief may be maintained by 1 Norflex Extended-release Tablet twice daily.

HOW SUPPLIED
TABLETS: Each round, white tablet imprinted with “3M” on one side and “221” on the other. Bottles of 100 (NDC **0089-0221-10**) and 500 (NDC **0089-0221-50**). Each tablet contains 100 mg of orphenadrine citrate.
INJECTION: Boxes of 6 (NDC **0089-0540-06**) 2 mL ampuls, each ampul containing 60 mg of orphenadrine citrate in aqueous solution.
Store at controlled room temperature 15º-30º (59º-86ºF).
Rx only
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Tablets Manufactured by
3M Pharmaceuticals
Northridge, CA 91324
Injection Manufactured for
3M Pharmaceuticals
Northridge, CA 91324
By Hospira, Inc.
Lake Forest, IL 60045
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